IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-662 (CFC) (CJB)
	)	
NATERA, INC.,	)	**REDACTED - PUBLIC VERSION**
	)	
Defendant.	)	

DEFENDANT NATERA, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGEMENT

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I. INTRODUCTION

CareDx alleges certain statements by Natera constitute false and misleading advertising under the Lanham Act and related state and common law. (D.I. 45.) CareDx primarily challenges Natera's statements that results from a clinical validation study of Natera's Prospera® product published in a peer-reviewed journal ("Sigdel") "compared favorably" to results from a separate clinical validation study on CareDx's AlloSure® product in a different journal ("Bloom"). At the pleading stage, CareDx argued that Natera's claims were false and misleading because: (1) Sigdel was unreliable, and (2) Sigdel and Bloom were not head-to-head studies that could support a comparison. (D.I. 40 at 3.)

Since then, CareDx has abandoned its first argument, and its executives and expert witness have admitted Sigdel *is* reliable. Indeed, Sigdel is a peer-reviewed publication; it is cited in other peer-reviewed papers in the kidney transplant field; and it formed the primary basis for Prospera's Medicare approval by an independent third party, MolDx. Now CareDx wants a jury to award it substantial damages because Natera said that its test "compared favorably" to CareDx's based on identified studies available for all to read.

To prove literal falsity, CareDx bears the burden of proving that the advertisements *make a literally false statement* regarding the methodology of the comparison; it cannot point to mere ambiguity or supposed methodological

differences that could *mislead or deceive* the audience. But CareDx does not, and cannot, assert that Natera ever represented that the studies were head-to-head studies or that the methodologies were identical; to the contrary, the advertisements expressly disclose that the assays were the subject of *separate* clinical studies and provide citations to those studies. Natera's claims reporting the results of the studies are, at most, ambiguous—and thus cannot be literally false as a matter of law.

Accordingly, CareDx's theory is really one of *misleadingness*, *i.e.*, that doctors reviewing Natera's advertisements will be *misled* regarding the methodologies of the underlying studies. That theory also fails as a matter of law because CareDx cannot prove actual consumer deception.

Because CareDx cannot prove that the advertising claims are literally false or misleading, or that CareDx suffered injury caused by the advertising, Natera is entitled to summary judgment on all three Counts in CareDx's Amended Complaint.

II. STATEMENT OF FACTS

The relevant facts are set forth in the Concise Statements of Facts ("SF").

III. SUMMARY JUDGMENT STANDARD

"Rule 56(c) mandates the entry of summary judgment ... against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "The burden on the moving

party may be discharged by pointing out . . . that there is an absence of evidence supporting the non-moving party's case. The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial." *Halosil Int'l, Inc. v. Eco-Evolutions, Inc.*, No. 18-cv-1375-RGA, 2020 WL 3971722, at *2 (D. Del. July 14, 2020).

IV. ARGUMENT

A. CAREDX'S FALSE ADVERTISING CLAIM FAILS.

In Count I, CareDx alleges false or misleading advertising under the Lanham Act, 15 U.S.C. § 1125(a). To establish its Lanham Act claim, CareDx bears the burden of proving that: (1) Natera has made false or misleading statements as to its own product or another's; (2) there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) the deception is material in that it is likely to influence purchasing decisions; (4) the advertised goods traveled in interstate commerce; and (5) there is a likelihood of injury to CareDx. *Pernod Ricard USA, LLC v. Bacardi USA, Inc.*, 653 F.3d 241, 248 (3d Cir. 2011). Natera is entitled to summary judgment because CareDx cannot prove elements one (falsity), two (deception), and five (injury/causation).[1] *See*, *e.g.*, *Halosil Int'l*, 2020 WL 3971722, at *4-5.

[1] Natera does not concede, and expressly reserves all rights to challenge, other elements of CareDx's claims not addressed in this Motion.

1. Natera's Advertising Claims Are Not False Or Misleading.

CareDx must prove that "the commercial message or statement is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." *Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). Critically, "only an *unambiguous* message can be literally false." *Id*. at 587 (emphasis in original). "In assessing whether an advertisement is 'literally false' a court must consider the message in full context." *American Home Prods. Corp. v. Procter & Gamble Co.*, 871 F. Supp. 739, 758 (D.N.J. 1994); *see Pernod Ricard USA*, 653 F.3d at 253.

a. Natera's "Establishment Claims" Are Not Literally False.

CareDx alleges that Natera made unlawful "establishment claims," *i.e.*, claims expressly or implicitly based on studies or testing. Specifically, CareDx challenges Natera's statements reporting results from Sigdel and Bloom or other peer-reviewed papers. (SF 12, 14-20.) As this Court recognized, "[t]he thrust of the Complaint is that Natera falsely and misleadingly suggested that the relevant studies show that Natera's product was superior to CareDx's product when in fact (1) the studies are not head-to-head studies that would support comparisons of the two competing products and (2) [Sigdel] is flawed and unreliable." (D.I. 40, at 3.)

CareDx must "show[] that the tests referred to ... were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited." *AstraZeneca LP v. Tap Pharm. Prod., Inc.*, 444 F. Supp. 2d 278, 294 (D. Del. 2006) (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992)). Alternatively, CareDx can satisfy its burden by proving that "the tests, even if reliable, do not establish the proposition asserted." *Castrol*, 977 F.2d at 63. "To ensure vigorous competition and to protect legitimate commercial speech, courts applying this standard should give advertisers a fair amount of leeway, at least in the absence of a clear intent to deceive or substantial consumer confusion." *Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow*, 93 F.3d 511, 515 (8th Cir. 1996).

i. CareDx Now Admits Sigdel Is Reliable.

Reversing its position from the pleading stage, CareDx now admits Sigdel is reliable,[2] and pursues only its second theory of literal falsity, *i.e.*, that the manner in which Natera's advertisements report the Sigdel results is literally false.

Specifically, CareDx's expert witness, Dr. Steven Weisbord, admitted that his "*opinion is not that the Sigdel paper is unreliable*, false, or scientifically unsupported

[2] CareDx's about-face is notable because the Court denied Natera's motion to dismiss based primarily on CareDx's allegations of unreliability. (D.I. 28, at 21, "the alleged unreliability of [Sigdel] constitutes the entire basis for CareDx's claim.")

in the abstract, *rather it is the way in which Natera uses* the Sigdel paper that is false and unreliable." (Ex. 39 at ¶ 19 (emphasis added); *see also* SF 5.)[3] Dr. Weisbord further admitted: "I don't dispute … that there is scientific validity to [Sigdel]. There are limitations to it. There are multiple reasons why the result shouldn't be compared to the Bloom study, but *I'm not claiming it is of no use or unreliable*." (Ex. 36 at 209:8-13 (emphasis added)). CareDx's Chief Executive Officer and Chief Marketing Officer made similar admissions. (*See* Ex. 31 at 108:8-10; Ex. 32 at 173:5-12.) These admissions were unavoidable given that Sigdel is published in a peer-reviewed journal, cited in other articles in peer-reviewed journals (including some that report the performance metrics from Sigdel and Bloom similarly to Natera's statements), and formed the primary basis for Prospera's Medicare reimbursement approval by an independent MolDx reviewer. (SF 9, 10); *see Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 974 (W.D. Wisc. 2010) ("[T]he fact that a peer-reviewed article was approved for publication is some evidence that the study is reliable."). Accordingly, CareDx cannot establish literal falsity by attacking the reliability of Sigdel.

[3] "Ex. __" refers to the exhibits to Declaration of Martin S. Masar submitted with Natera's Concise Statement of Facts.

ii. Sigdel, Bloom, and Huang Establish the Claimed Propositions.

Because Sigdel is reliable, CareDx must prove that "the [study/ies], even if reliable, do not establish the proposition asserted." *Castrol*, 977 F.2d at 63; *Riddell*, 724 F. Supp. 2d at 975-76. CareDx cannot do so by conflating this requirement with the "reliability" requirement and arguing that Sigdel is flawed. *Procter & Gamble Co. v. Chesebrough–Pond's, Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) ("The mere fact that one party's evidence in support of the truth of its advertisements was unpersuasive would not *ipso facto* entitle the other party to relief ... regardless of the weaknesses of the tests made and relied on by [defendant]"). Consequently, even if CareDx's "concerns about the study give reasons to doubt the results of the study ... they do not show that the study was unreliable." *Riddell*, 724 F. Supp. 2d at 974.

CareDx must prove that Sigdel's results and conclusions do not support the claims made in Natera's advertising or that the study was irrelevant to the claimed proposition. *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1249 (11th Cir. 2002) ("The fact that a study's design is imperfect, however, does not render [the] advertisements false. J&J cannot prove that the [study] reached a conclusion different from the proposition cited in the [advertisements]."); *Castrol*, 977 F.2d at 63-64 (plaintiff proved that tests regarding "faster oiling time" were "irrelevant" to defendant's claims that its oil "protects better at startup;" such "irrelevant" testing did not establish the proposition asserted). CareDx cannot do so

for the simple reason that Natera's advertising accurately reported the results of Sigdel and Bloom. Sigdel established that Prospera had an AUC of .87, a sensitivity of 88.7%, and an NPV of 95.1% and Bloom reported that AlloSure had an AUC of 0.74, a sensitivity of 59%, and an NPV of 84%. (SF 4, 6, 14 (and citations therein)). Natera's advertisements accurately report that data. Likewise, Natera's advertising claims accurately reported the results of Sigdel, Bloom, and the Huang Paper (a second paper citing clinical performance results for Allosure) by touting Prospera's ability to accurately detect two prevalent types of rejection (*i.e.*, t-cell mediated rejection or "TCMR," and subclinical rejection) while AlloSure could not. (SF 4, 6, 7, 17, 18.) It is indisputable that Prospera accurately detected 10 of 10 cases of TCMR in Sigdel, while CareDx's AlloSure product *missed* 8 of 11 TCMR cases in the Bloom Paper and *missed* 7 of 10 TCMR cases in Huang. (*Id.*) It is also indisputable that Sigdel demonstrated that Prospera correctly detected 12 of 13 cases of subclinical rejection and neither Bloom nor any other study published at the time of Natera's advertisements demonstrated that AlloSure could detect subclinical rejection. (*Id.*) Thus, Natera's advertisements accurately reporting those facts are not literally false. *See Riddell*, 724 F. Supp. 2d at 975-76 (summary judgment granted where establishment claims "cannot be literally false" because the underlying study is reliable and the claims state "exactly what the study shows").

Similarly, Natera's statement that its product "compares favorably against competition" cannot be literally false, because it is literally true (or at worst ambiguous). *Novartis*, 290 F.3d at 587. Moreover, Sigdel plainly shows that Prospera does "compare favorably" to AlloSure on the cited attributes.[4] Further, Natera's advertising not only accurately reports data from the studies, but it also cites to the peer-reviewed papers, so the audience—primarily sophisticated healthcare professionals—can review the studies, methodologies, results, and conclusions for themselves. (*See* Ex. 36 at 102:12-105:5) (CareDx's expert admitting "I think that ... physicians may very well pull up the papers. I think many physicians would look at the abstract, and they can get an idea of what study design is. And they can get an idea of what the study looked at, and they can get the main takeaway messages from the study.").

[4] CareDx also challenges Natera's SEC Form 8-K investor presentation stating that Prospera "Outperforms Competition." (Ex. 6 at Slide 10). That claim cannot be literally false because a) it is ambiguous as to what is being compared, and b) the underlying studies *do* show that Prospera "outperformed" AlloSure on the cited metrics. Moreover, allegations regarding SEC filings or prospectus documents fail as a matter of law because such documents are disseminated to prospective investors, not prospective customers. *See Cancer Genetics, Inc. v. Hartmayer*, No. CIV. 07-5463(FSH), 2008 WL 323738, at *10 (D.N.J. Feb. 5, 2008) ("Courts ... have been clear in requiring the involvement of a 'customer' or 'consumer' as those terms are generally understood .... Plaintiff does not cite a single case in which a court has equated "investor" with "customer" for purposes of § 1125(a)(1)(B)."); *C=Holdings B.V. v. Asiarim Corp.*, 992 F.Supp.2d 223, 243-44 (S.D.N.Y. 2013).

Natera's statements accurately reporting data from reliable studies, and citing to the studies, cannot be literally false in context. Instead, CareDx's theory is really one of *misleadingness*, *i.e.*, that doctors reviewing Natera's advertisements will be *misled* regarding the methodology of the comparison. That distinction is critical because misleading claims require a higher showing (*e.g.*, actual deception) that CareDx cannot make. (*See* Section I.A.2. *infra*.)

Johnson & Johnson is instructive. In that case, the defendant advertised the results of a study finding that a certain contact lens brand was "preferred 5 to 1" over plaintiff's contact lens brand. *Johnson & Johnson Vision Care*, 299 F.3d at 1248. The plaintiff did not contest the reliability of the preference study. *Id*. at 1249 n.6. The district court held that the advertisement "misrepresented to consumers the superiority of [the preferred lens]" by failing to "make it clear to the consumer that the study was comparing modalities (*i.e.* length of time wearing the lens, one day wear versus two week wear) and not the quality of lenses with the same modality." *Id*. On appeal, the Eleventh Circuit held that the defendant's establishment claims could not be literally false. *Id*. at 1249, 1252. Although the testing was "imperfect," the plaintiff had nevertheless failed to "prove that the [study] reached a conclusion different from the proposition cited in the [advertisements]." *Id*. at 1249. The study did find a five to one preference, and the advertisement stated that the study compared a one-day lens to a two-week lens. Although the advertisement included

the preference claim in places *without* clarifying the specifics of the testing, even then, "[t]he best case that a plaintiff could make is that the letter is misleading" rather than literally false. *Id*. at 1249 n.5.

Here, the crux of CareDx's argument is that Sigdel's "methodology differs so significantly from the Bloom Study's methodology that comparison claims are precluded." (D.I. 45, at ¶ 41.) This is a red herring. The Lanham Act does not "preclude" a comparison of two or more reliable studies that have different methodologies. *Pfizer, Inc. v. Miles, Inc*., 868 F. Supp. 437, 455-56 (D. Conn. 1994) (establishment claim based on cross-study comparison rather than head-to-head study was not literally false or misleading); *Procter & Gamble*, 747 F.2d at 120 (affirming establishment claims were not literally false despite underlying testing not being conducted head-to-head). CareDx bears the burden to prove that the advertisements make a literally false statement regarding the methodology of the comparison; it cannot point to mere ambiguity or supposed methodological differences that *could mislead or deceive* the audience. *American Home Prods.*, 871 F. Supp. at 759-60. In other words, absent a facially false representation regarding the methodology of the comparison, it is at most an *ambiguity*, which cannot be literally false. *Pfizer*, 868 F. Supp. at 455-56 (holding defendant's establishment claim not literally false even though it was based on a cross-study comparison rather than a head-to-head study "because the conclusions reported in both the 'Lewis

study' and the 'Adalat CC Product Monograph' are not literally false, and are based upon reliable tests, the issue becomes whether a cross-study comparison of the two tests 'is likely to mislead and confuse consumers'"); *Novartis*, 290 F.3d at 587. Natera's advertisements *never state* that the claims are based on a head-to-head study. Rather, as in *Johnson & Johnson*, Natera's advertisements explicitly cite the *separate* Sigdel and Bloom papers (among other studies), making plain that the claims are not based on a single head-to-head study. In fact, CareDx's expert admitted that physicians viewing Natera's advertisements would "look at the different citations and glance at the abstracts and understand that they were done in different patient populations," *i.e.*, that the studies were not head-to-head. (Ex. 36 at 150:7-151:15). Thus, Natera's advertisements cannot be *literally false*. And, like in *Pfizer* and *Johnson & Johnson*, CareDx's theory based on differences in the study methodologies is, at best, a theory of misleadingness (which also fails). 868 F. Supp. at 455; 299 F.3d at 1249.[5]

[5] Previously, this Court noted "as set forth in the Complaint," Natera's advertisements "*suggest* a head-to-head study." (D.I. 40 at 4) (emphasis added). Whether advertisements *suggest* a message to the audience is a question of misleadingness, not literal falsity. *Riddell*, 724 F.Supp.2d at 977 ("At most, such a context *suggests* that the study had a broad study group or that the results can be applied to the audience. This means the advertisements may be misleading, not that they are literally false.") (emphasis in original).

b. CareDx Cannot Prove That Natera's Establishment Claims Are Misleading.

Because CareDx cannot prove literal falsity, it must retreat to its fallback position that Natera's claims are misleading. Misleadingness, however, requires an even higher showing – proving actual deception. *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228-29 (3d Cir. 1990) (plaintiff "cannot obtain relief by arguing how consumers *could* react; it must show how consumers *actually do* react.") (emphasis in original). To show actual deception, CareDx must submit evidence demonstrating that a "substantial portion of the intended audience" is deceived by each of the challenged advertising claims. *Johnson & Johnson-Merck Consumer Pharm. Co. v. Rhone-Poulenc Rorer Pharm., Inc.*, 19 F.3d 125, 129, 132-136 (3d Cir. 1994) (granting defendant's summary judgment motion because flawed survey was insufficient to prove a substantial portion of the intended audience was deceived; "If Rorer's commercials do mislead consumers into thinking that ESMP promises superior relief, well-designed consumer surveys will show that they do. Absent such evidence, neither the district court nor this court can conclude that consumers were misled."); *American Home Prods.*, 871 F. Supp. at 760 ("Because '[p]ublic reaction is the measure of a commercial's impact,' an implied falsity claim must be proven in a false advertising case via the use of a consumer survey.") (quoting *Johnson & Johnson–Merck*, 19 F.3d at 129-30); *AstraZeneca*, 444 F. Supp. 2d at 296 ("[T]o prevail on its implied false advertising claims, TAP must show,

through its consumer surveys, that consumers were actually misled by AstraZeneca's advertising."). It is indisputable that CareDx has not submitted survey evidence or any other admissible evidence proving that a substantial portion of the intended audience was actually deceived. CareDx has simply ignored that requirement. Its misleadingness theory fails as a matter of law for that reason alone.

c. Natera's Non-Establishment Claims Are Not Literally False or Misleading.

CareDx also challenges other Natera statements that are not establishment claims. But that challenge also fails as a matter of law.

CareDx challenges Natera's June-July 2018 statements regarding the number of patients and samples involved in the UCSF study because some of those patients and samples were excluded from later drafts of the Sigdel paper in the fall of 2018—*after* Natera made the claims. (SF. 12.) Natera's statements are not actionable because they were based on the data presented by the study's investigator at a conference at that time (Ex. 29 at NTRA044920-22, NTRA044928, SF. 12), and the Lanham Act inquiry is whether statements "are false or misleading at the time they are made." *Alpo Petfoods, Inc. v. Ralston Purina Co.*, 720 F. Supp. 194, 205 n. 12 (D.D.C. 1989), *rev'd in part on other grounds*, 913 F.2d 958 (D.C. Cir. 1990).

CareDx also challenges a statement in two Natera presentations that states the Prospera test is "Highly sensitive across a range of rejection types and patients," and lists the racial and age demographics for the entire study. (SF. 19.) CareDx

misinterprets this as a claim that Prospera is highly sensitive in a pediatric population. (*Id.*; Ex. 38 at ¶¶189-202.) The presentation makes no such claim. (*Id.*) CareDx's misinterpretation relies on an ambiguity at worst, which cannot be literally false. *Novartis*, 290 F.3d at 587.

Finally, CareDx takes issue with Natera's statements that Prospera is "most precise" or provides "unparalleled precision." (SF. 20.) But even CareDx's expert Dr. Weisbord admitted that the terms "precision" and "precise" are ambiguous and susceptible to different meanings among the relevant audience of doctors. (Ex. 36 at 86:14-93:17; 269:7-271:4; 291:17-292:5; 310:17-311:4). Thus, these claims are again at worst ambiguous and cannot be literally false as a matter of law. *Novartis*, 290 F.3d at 587. And, as discussed *supra*, those claims also cannot be misleading because CareDx has not adduced evidence of actual deception of a substantial portion of the intended audience.

* * * * *

CareDx cannot prove the first two required elements of its Lanham Act false advertising claim, namely, that Natera's advertising claims are (a) literally false, or (b) misleading and caused actual deception. Thus, CareDx's Lanham Act claim fails as a matter of law. *Halosil Int'l*, 2020 WL 3971722, at *4-5 (summary judgment granted where plaintiff failed to prove challenged claims were false or misleading).

2. CareDx Has Adduced No Evidence of Injury.

CareDx must also "prove[] an injury to a commercial interest in sales or business reputation *proximately caused by* the defendant's misrepresentations." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 140 (2014) (emphasis added). CareDx must bring forth evidence of both actual damages (because it seeks monetary damages) and "likely" harm (because it seeks injunctive relief). *Synygy, Inc. v. ZS Assocs., Inc.*, 110 F. Supp. 3d 602, 621-22 (E.D. Pa. 2015) ("A party seeking both an injunction and damages ... must meet both the standard of proof for an injunction as well as that for damages").

First, CareDx cannot recover monetary damages because it has failed to adduce any competent evidence of "customer reliance." *See Parkway Baking Co. v. Freihofer Baking Co.*, 255 F.2d 641, 648 (3d Cir. 1958); *Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 92 (3d Cir. 2000) (noting that, in Third Circuit, "a plaintiff seeking damages under [Section] 43(a) must establish customer reliance"); *see also U.S. Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 922 (3d Cir. 1990). Absent such evidence, CareDx cannot "establish[] a causal link between the damages and the defendant's conduct." *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 969 (D.C. Cir. 1990). CareDx's damages expert merely *assumes* that Natera's profits and market share are attributable to misconduct, as opposed to ordinary competition. (Ex. 40 at 3, 31, 46-48). This is impermissible.

See Verisign, Inc. v. XYZ.COM LLC, 848 F.3d 292, 300–01 (4th Cir. 2017) (damages report excluded where "fatal flaw" was to "assume[] rather than demonstrate[]" that plaintiff's lost sales were due to defendant's false statements); *see also Larry Pitt & Assocs. v. Lundy Law LLP*, 294 F. Supp. 3d 329, 342 (E.D. Pa. 2018); *Am. Home Prod. Corp. v. Johnson & Johnson*, 682 F. Supp. 769, 771 (S.D.N.Y. 1988) (dismissing false-advertising claim where plaintiff relied on the "highly questionable premise[]" that a product's entire sales decline "is attributable to false and misleading advertising by [defendant]").

CareDx's bases for causation and injury rest principally on its own self-serving interrogatory responses and deposition testimony from its CEO, Peter Maag, which, as discussed below, shows *no* reliance. (Ex. 40 at 2). The only other "evidence" is [redacted] (Ex. 47 at CAREDXNA662_00014795). In addition to being inadmissible double hearsay, the email does not actually speak to causation—rather, it is general conjecture about the effect of Natera's campaign, which is insufficient to prove damages. *Synygy*, 110 F. Supp. 3d at 623 (granting summary judgment of no damages where plaintiff presented only hearsay conversation as evidence of injury); *Syncsort Inc. v. Innovative Routines Int'l, Inc.*, No. 04-cv-3623 (WHW), 2008 WL

1925304, *11 (D.N.J. Apr. 30, 2008) (plaintiff failed to "point to evidence that customers were actually deceived or relied on the advertising statement"). Without competent evidence of causation, CareDx cannot show "customer reliance on the false advertisement," which this Circuit has long required for monetary damages. *Parkway Baking*, 255 F.2d at 648.

CareDx's failure to prove monetary damages precludes recovery of *any* monetary award, including corrective advertising. *See Larry Pitt*, 294 F. Supp. 3d at 342–43 ("[B]ecause [plaintiff] has not established entitlement to disgorgement or money damages, corrective advertising cannot be justified as a surrogate for such recovery."); *Quidel Corp. v. Siemens Med. Sols. USA, Inc.*, No. 16-CV-3059-BAS-AGS, 2020 WL 4747724, at *8 (S.D. Cal. Aug. 17, 2020) (corrective advertising damages improper where there was "no evidence that [plaintiff] was damaged by [the] advertising as it relates to physicians, so it [could not] now recover for amounts spent correcting that advertising"); *ALPO*, 913 F.2d at 969 (causal link required for all categories of damages, including corrective advertising). CareDx presents no evidence of injury or causation and thus "has not met its burden to set forth sufficient evidence of consumer deception to support a claim for monetary damages under the Lanham Act." *Synygy*, 110 F. Supp. 3d at 623.

CareDx also fails to demonstrate a likelihood of economic injury as required for injunctive relief. Merely showing "direct competition between the parties" is

insufficient. *Newborn Bros. Co. v. Albion Eng'g Co.*, No. 12-cv-2999 (NLH/KMW), 2020 WL 5015571, *35 (D.N.J. Aug. 25, 2020). Rather, CareDx must "prove that there is 'a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising.'" *Id.* (quoting *Warner–Lambert*, 204 F.3d at 95). But CareDx has repeatedly insisted that Natera's market activity *benefits* CareDx—having Natera "talk about cell free DNA testing [was] not negative for CareDx," as CareDx was "the predominant provider of these solutions at this stage"; it viewed competitive "noise" as irrelevant and expected "competition [to] expand[] our market and increase[] the opportunity for accelerated growth"; and that it saw itself "well-positioned" in 2020 to "build out its first mover advantage." (SF. 24.) CareDx's CEO admitted Natera was "[redacted]" (Ex. 31 at 77:11-14; 91:3-94:10.) Of course, fear of ordinary competition cannot justify Lanham Act remedies.

Public averments and sworn testimony demonstrate CareDx has no reasonable basis to believe Natera's advertising presents a cognizable likelihood of harm. CareDx is not entitled to an injunction as a matter of law.

B. CAREDX'S UNFAIR COMPETITION CLAIM FAILS.

Count II for unfair competition requires CareDx to prove: (1) a "reasonable expectancy of entering a valid business relationship" and (2) defendant's "wrongful[] interfere[nce]," which (3) "defeats the plaintiff's legitimate expectancy"

and (4) "causes him harm." *Rypac Packaging Mach. Inc. v. Coakley*, No. CIV. A. 16069, 2000 WL 567895, at *8 (Del. Ch. May 1, 2000). "[T]o the extent [it] exists as an independent common-law tort," this is "essentially the same tort [as] tortious interference with prospective business relations," *Preston Hollow Capital LLC v. Nuveen LLC*, 216 A.3d 1, 15 n. 96 (Del. Ch. 2019), and requires "factual support" that "a business relationship with a specific party was reasonably probable." *Nespresso USA, Inc. v. Ethical Coffee Co. SA*, No. 16-cv-194-GMS, 2016 WL 11697058, *1 n.1 (D. Del. Sept. 7, 2016).

CareDx cannot satisfy any element of the claim. First, as discussed above, CareDx cannot show that Natera's statements were false or misleading; therefore, it cannot demonstrate wrongful interference. Second, CareDx also cannot establish that it had a "reasonable expectancy" of any specific valid business relationship with which Natera specifically interfered. *Agilent Techs., Inc. v. Kirkland*, No. CIV.A. 3512-VCS, 2009 WL 119865, at *7 (Del. Ch. Jan. 20, 2009). Finally, as discussed above, CareDx has repeatedly *denied* that Natera had any adverse effect on CareDx's business, insisting that Natera's market entry *helped* CareDx by legitimatizing dd-cfDNA technology. CareDx's failure to present evidence of actual injury or harm defeats its common-law claim. *See Tri-State Energy Sols., LLP v. KVAR Energy Sav. Inc.*, 884 F. Supp. 2d 168, 182–83 (D. Del. 2012). This claim fails as a matter of law.

C. CAREDX'S DELAWARE STATUTORY CLAIM FAILS.

Count III regarding the Delaware Uniform Deceptive Trade Practices Act ("DTPA") requires CareDx to "show injury to a 'business or trade interest' that is caused by the defendant's 'interference by unfair or deceptive trade practices.'" *Emerson Elec. Co. v. Emerson Quiet Kool Co.*, No. 17-cv-1846-LPS, 2019 WL 1397244, *4 (D. Del. Mar. 28, 2019). The DTPA affords no greater protection than the Lanham Act. *See Textron*, 499 F. Supp. at 249 n.17. Because CareDx has adduced no proof of injury or causation, Natera is entitled to summary judgment on Count III as well.

V. CONCLUSION

CareDx cannot prove all required elements of the three Counts in its Amended Complaint as a matter of law, and Natera thus respectfully requests summary judgment in its favor on all three Counts.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations specified in Local Rule 7.1.3 and the Court's November 6, 2019 Standing Order Regarding Briefing in All Cases. According to the word processing system used to prepare this document, the brief contains 4,907 words. This total excludes the cover page, signature block, the table of contents, the table of authorities, and certification.

I further certify that this brief complies with the typeface requirements set forth in the Court's November 6, 2019 Standing Order Regarding Briefing in All Cases because this brief was prepared using Microsoft Word in 14-point Times New Roman font.

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